K014168

APR 2 5 2002

510(k)
AU6 Technos/Technos MP Ultrasound Imaging System
Biosound Esaote

510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Colleen Hittle Densmore, Official Correspondent
8000 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 849-1916
Facsimile: (317) 577-9070

Contact Person: Colleen Hittle Densmore

Date: December 11, 2001

807.92(a)(2)

Trade Name:	AU6 (Technos/Technos MP) Ultrasound Imaging System (Addition of 3D Imaging Mode and Musculoskeletal Indication)	
Common Name:	Ultrasound Imaging System	
Classification Name(s):	Ultrasonic pulsed doppler imaging system	892.1550
Classification Number:	90IYN 90IYO	

807.92(a)(3)

Predicate Device(s)

Esaote	AU6 (Technos/TechnosMP)	K990360
Esaote	AU5 3D	K000931

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

510(k)
AU6 (Technos/TechnosMP) Ultrasound Imaging System
Biosound Esaote

807.92(a)(5)

Intended Use(s)

The AU6 (Technos/TechnosMP) ultrasound imaging system is intended to be used by a physician for diagnostic imaging in pediatric, small organ, neonatal cephalic, transrectal, transvaginal, intraoperative abdominal, intraoperative peripheral vascular, laparoscopic, adult cephalic and musculoskeletal applications.

510(k) Summary
AU6 (Technos/TechnosMP) Ultrasound Imaging System
Biosound Esaote

Comparison Chart for Substantial Equivalence

General Characteristic	Esaote AU5 3D (K000931)	Esaote AU6 Digital (Technos) (K990360)	Esaote Technos/Technos^{MP} This Submission 3D/Musculoskeletal
Transducer Type			
Linear Array	YES	YES	YES
Convex Array	YES	YES	YES
Phased Array	NO	YES	YES
Pencil	NO	YES	YES
Imaging Modes of Operation			
A Mode	NO	NO	NO
B Mode	YES	YES	YES
M Mode	YES	YES	YES
PWD (PW)	YES	YES	YES
CWD	NO	YES	YES
(Color Doppler) CFM	YES	YES	YES
(Amplitude Doppler) PD	YES	YES	YES
Color Velocity Imaging	NO	NO	NO
Combined (B+PW+CFM+PD+M)	YES	YES	YES
Duplex	YES	YES	YES
Triplex	YES	YES	YES
TEI/CTEI	YES	YES	YES
Modules			
ECG	YES	YES	YES
Cardio	NO	YES	YES
3D	YES	NO	YES
Clinical Applications			
Obstetric/Fetal	YES	YES	YES
Abdominal	YES	YES	YES
Intra-operative	YES	YES	YES
Pediatric	YES	YES	YES
Small Organ	YES	YES	YES
Neonatal Cephalic	YES	YES	YES
Adult Cephalic	YES	YES	YES
Cardiac	YES	YES	YES
Trans-esophageal	NO	YES	YES
Trans-rectal	YES	YES	YES
Trans-vaginal	YES	YES	YES
Peripheral Vascular	YES	YES	YES
Laparoscopic	YES	YES	YES
Muscolo-skeletal Conventional	NO	NO	YES
Muscolo-skeletal Superficial	NO	NO	YES
Urological	NO	YES	YES
Miscellaneous			
Biopsy attachments	YES	YES	YES
Display type	SVGA	SVGA	SVGA
VCR/Printer	Yes	Yes	Yes
Electrical safety	IEC 60601-1	IEC 60601-1	IEC 60601-1
Ultrasound safety	Track 3	Track 3	Track 3
Digital Archival	Yes	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Colleen J. Densmore
Official Correspondent
The Anson Group
7992 Castleway Drive
INDIANAPOLIS IN 46250

APR 2 5 2002

Re: K014168
Trade Name: AU6 (Technos/Technos MP) Ultrasound Imaging System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasound transducer
Regulatory Class: II
Product Code: 90 IYN, IYO, and ITX
Dated: March 28, 2002
Received: April 1, 2002

Dear Ms. Densmore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the AU6 (Technos/Technos MP) Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number
IOE323
LA424
LA522E
LA523
CA123
CA421
CA621

CAB411A
EC123
LP323
TRT23
PA220E
PA122E

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Technos /Technos^{MP} System

3D DSM2 & DSM3 / Musculoskeletal

Appendix F

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P		P (1)	P (3) N (2)
Abdominal		P	P	P	P	P	P		P (1)	P (3) N (2)
Intraoperative Abdominal		P	P	P		P	P		P (1)	P (3) N (2)
Intraoperative Peripheral vascular		P	P	P		P	P		P (1)	P (3) N (2)
Intraoperative Neurological										
Pediatric		E	E	E	E	E	E		E (1)	E(3) N (2)
Small Organ (specify)		P	P	P		P	P		P (1)	P (3) N (2)
Neonatal Cephalic		P	P	P	P	P	P		P (1)	P (3) N (2)
Adult Cephalic		P	P	P	P	P	P		P (1)	P (3) N (2)
Cardiac		P	P	P	P	P	P		P (1)	P (3) N (2)
Transesophageal		P	P	P	P	P	P		P (1)	P (3) N (2)
Transrectal		P	P	P		P	P		P (1)	P (3) N (2)
Transvaginal		P	P	P		P	P		P (1)	P (3) N (2)
Intravascular										
Peripheral Vascular		P	P	P	P	P	P		P (1)	P (3) N (2)
Laparoscopic		P	P	P		P	P		P (1)	P (3) N (2)
Musculoskeletal Conventional		N	N	N		N	N		N(1)	N(3)
Muscoloskeletal Superficial		N	N	N		N	N		N(1)	N(2)
Other (Urological)		P	P	P		P	P		P (1)	P (3) N (2)

N= new indication; P= previously cleared by FDA; E= added under Appendix F

Additional Comments:
Small Organs (specifically, thyroid, testicles and breast);
Peripheral Vascular to include Vein Mapping & Sclerotherapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.
Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): 3D-DSM2/DSM3

Note (3): TEI (Tissue Enhanced Imaging) mode (AU6 system was cleared for TEI via K000681)

Prescription Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K014168

IOE323

3D & Musculoskeletal

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Obstetric/Fetal										
Abdominal										
Intraoperative (Abdominal)		E	E	E		E	E		E (1)	N(2)
Intraoperative (Peripheral vascular)		E	E	E		E	E		E (1)	N(2)
Pediatric		E	E	E		E	E		E (1)	N(2)
Small Organ (specify)		E	E	E		E	E		E (1)	N(2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Inhtravascular										
Peripheral Vascular		E	E	E		E	E		E (1)	N(2)
Laparoscopic										
Muscoloskeletal Conventional		N	N	N		N	N		N(1)	N(2)
Muscoloskeletal Superficial		N	N	N		N	N		N(1)	N(2)
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
Small Organs (specifically, thyroid, testicles and breast);
Peripheral Vascular to include Vein Mapping & Sclerotherapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): 3D-DSM2

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K014168

LA424

3D & Musculoskeletal

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E	E		E	E		E (1)	N(2)
Small Organ (specify)		E	E	E		E	E		E (1)	N(2)
Neonatal Cephalic										
Adult Cephalic/Transcranic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Inhtravascular										
Peripheral Vascular		E	E	E		E	E		E (1)	N(2)
Laparoscopic										
Muscoloskeletal Conventional		N	N	N		N	N		N (1)	N(2)
Muscoloskeletal Superficial		N	N	N		N	N		N (1)	N(2)
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
Small Organs (specifically, thyroid, testicles and breast);
Peripheral Vascular to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live

Note (2): 3D-DSM2/DSM3

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K014168

Prescription Use ✓
(Per 21 CFR 801.109)

LA522E

3D & Musculoskeletal

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E	E		E	E		E (1)	N(2)
Small Organ (specify)		E	E	E		E	E		E (1)	N(2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Inhtravascular										
Peripheral Vascular		E	E	E		E	E		E(1)	N(2)
Laparoscopic										
Muscoloskeletal Conventional		N	N	N		N	N		N (1)	N(2)
Muscoloskeletal Superficial		N	N	N		N	N		N (1)	N(2)
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix I

Additional Comments:
Small Organs (specifically, thyroid, testicles and breast);
Peripheral Vascular to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live
Note (2): 3D-DSM2/DSM3

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K014168

LA523

3D & Musculoskeletal

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E	E		E	E		E (1)	N(2)
Small Organ (specify)		E	E	E		E	E		E (1)	N(2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Inhtravascular										
Peripheral Vascular		E	E	E		E	E		E (1)	N(2)
Laparoscopic										
Muscoloskeletal Conventional		N	N	N		N	N		N (1)	N(2)
Muscoloskeletal Superficial		N	N	N		N	N		N (1)	N(2)
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
Small Organs (specifically, thyroid, testicles and breast);
Peripheral Vascular to include Vein Mapping & Sclerotherapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.
Note (2): 3D-D$M/DSM3

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K014168

Prescription Use ✓
(Per 21 CFR 801.109)

CA123
3D

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		E	E	E		E	E		E (1)	N(2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E	E		E	E		E (1)	N(2)
Small Organ (specify)		E	E	E		E	E		E (1)	N(2)
Neonatal Cephalic		E	E	E		E	E		E (1)	N(2)
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		E	E	E		E	E		E (1)	N(2)
Laparoscopic										
Muscoloskeletal Conventional										
Muscoloskeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
Small Organs (specifically, thyroid, testicles and breast);
Peripheral Vascular to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.
(2): 3D-DSM2

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K014168

Prescription Use ✓
(Per 21 CFR 801.109)

CA421
3D

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophtalmic										
Fetal		E	E	E		E	E		E (1)	E(3) N(2)
Abdominal		E	E	E		E	E		E (1)	E(3) N(2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E	E		E	E		E (1)	E(3) N(2)
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		E	E	E		E	E		E (1)	E(3) N(2)
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		E	E	E		E	E		E (1)	E(3) N(2)
Laparoscopic										
Muscoloskeletal Conventional										
Muscoloskeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
Peripheral Vascular to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.
Note (2): 3D-DSM2/DSM3
Note (3): TEI (Tissue Enhanced Imaging) mode (AU6 system was cleared for TEI via 5000681)

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of **Reproductive, Abdominal,** and Radiological **Devices**
510(k) Number K014168

CA621
3D

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophtalmic										
Fetal		E	E	E		E	E		E (1)	E(3) N(2)
Abdominal		E	E	E		E	E		E (1)	P(3) N(2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E	E		E	E		E (1)	P(3) N(2)
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		E	E	E		E	E		E (1)	E(3) N(2)
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Inhtravascular										
Peripheral Vascular		E	E	E		E	E		E (1)	P(3) N(2)
Laparoscopic										
Muscoloskeletal Conventional										
Muscoloskeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
Peripheral Vascular to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.
Note (2): 3D-DSM2-DSM3
Note (3): TEI (Tissue Enhanced Imaging) mode (AU6 system was cleared for TEI via K000681)

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K014168

CAB411A
3D

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E	E		E	E		E (1)	E(3) N(2)
Abdominal		E	E	E		E	E		E (1)	P(3) N(2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Inhtravascular										
Peripheral Vascular		E	E	E		E	E		E (1)	P(3) N(2)
Laparoscopic										
Muscoloskeletal Conventional										
Muscoloskeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
Note (1): Combinations: any combination of the following modes: B+M+PW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.
Note (2): 3D-DSM2
Note (3): TEI (Tissue Enhanced Imaging) mode (AU6 system was cleared for TEI via K000681)

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K014168

EC123
3D

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E	E		E	E		E (1)	N(2)
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		E	E	E		E	E		E (1)	N(2)
Transvaginal		E	E	E		E	E		E (1)	N(2)
Transurethral										
Inhtravascular										
Peripheral Vascular										
Laparoscopic										
Muscoloskeletal Conventional										
Muscoloskeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note (1): Combinations: any combination of the following modes: B+M+PW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.
Note (2): 3D-DSM2/DSM3

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K014168

LP323
3D

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Inhtravascular										
Peripheral Vascular		N	N	N		N	N		N(1)	N(2)
Laparoscopic		E	E	E		E	E		E (1)	N(2)
Muscoloskeletal Conventional										
Muscoloskeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note (1): Combinations: any combination of the following modes: B+M+PW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.
Note (2): 3D-DSM2

Prescription Use ✓
(Per 21 CFR 801.109)

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510(k) Number K014168

TRT23
3D

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-operative (specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		E	E	E		E	E		E (1)	N(2)
Transvaginal		E	E	E		E	E		E (1)	N(2)
Transurethral										
Inhtravascular										
Peripheral Vascular										
Laparoscopic										
Muscoloskeletal Conventional										
Muscoloskeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note (1): Combinations: any combination of the following modes: B+M+PW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.
Note (2): 3D-DSM2

Prescription Use 2
(Per 21 CFR 801.109)

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PA220E
3D

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		E	E	E	E	E	E		E (1)	N (2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic		E	E	E	E	E	E		E (1)	N (2)
Cardiac		E	E	E	E	E	E		E (1)	E(3) N (2)
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Inhtravascular										
Peripheral Vascular										
Laparoscopic										
Muscoloskeletal Conventional										
Muscoloskeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW. B+M, B+CFM+PW where all single modes are live.
Note (2): 3D-DSM2
Note (3): TEI (Tissue Enhanced Imaging) mode (AU6 system was cleared for TEI via K000681)

Prescription Use ✓
(Per 21 CFR 801.109)

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510(k) Number K014168

PA122E
3D

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E	E	E	E	E		E(1)	N(2)
Small Organ (specify)										
Neonatal Cephalic		E	E	E	E	E	E		E(1)	N(2)
Adult Cephalic										
Cardiac		E	E	E	E	E	E		E(1)	N(2)
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Inhtravascular										
Peripheral Vascular		E	E	E	E	E	E		E(1)	N (2)
Laparoscopic										
Muscoloskeletal Conventional										
Muscoloskeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
Peripheral Vascular to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.
Note (2): 3D-DSM2

Prescription Use C
(Per 21 CFR 801.109)

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510(k) Number K014168